

Substitute for Form 1449/A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

## Complete if Known

Application No.	09/780,650
Filing Date	02/12/2001
First Named Inventor	D'Amato
Group Art Unit	1616
Examiner Name	Badio, Barbara P.
Attorney Docket Number	05213-0493 (43170-253692)

Sheet 1 of 31

## U.S. PATENT DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number <sup>2</sup>	Kind Code <sup>3</sup> (if known)			
BB	1	2,584,271		Huffman	02/05/1952	
	2	2,846,453		Hoehn	08/05/1958	
	3	3,166,577		Ringold et al.	01/19/1965	RECEIVED
	4	3,410,879		Smith et al.	11/12/1968	OCT 01 2004
	5	3,470,218		Farah	09/30/1969	OFFICE OF PETITIONS
	6	3,492,321		Crabbe	01/27/1970	
	7	3,496,272		Kruger (Identifier only)	02/17/1970	
	8	3,562,260		De Ruggieri et al.	02/09/1971	
	9	3,956,348		Hilscher	05/11/1976	
	10	4,212,864		Tax	07/15/1980	
	11	4,307,086		Tax	12/22/1981	
	12	4,552,758		Murphy et al.	11/12/1985	
	13	4,634,705		DeBernardis et al.	01/06/1987	
	14	4,808,402		Leibovich et al.	02/28/1989	
	15	4,994,443		Folkman et al.	02/19/1991	
	16	5,135,919		Folkman et al.	08/04/1992	
	17	5,521,168		Clark	05/28/1996	
	18	5,621,124		Seilz et al.	04/15/1997	
	19	5,629,340		Kuwano et al.	05/13/1997	
	20	5,639,725		O'Reilly et al.	06/17/1997	
	21	5,716,981		Hunter et al.	02/10/1998	
	22	5,733,876		O'Reilly et al.	03/31/1998	
	23	5,763,432		Tanabe et al.	06/09/1998	
BB	24	5,776,704		O'Reilly et al.	07/07/1998	

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of

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First Named Inventor

D'Amato

Group Art Unit

1616

Examiner Name

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05213-0493 (43170-253692)

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		Number <sup>2</sup>	Kind Code <sup>3</sup> (if known)			
BZ	25	5,792,845		O'Reilly et al.	08/11/1998	
	26	5,837,682		O'Reilly	11/17/1998	
	27	5,854,205		O'Reilly et al.	12/29/1998	
	28	5,854,221		Cao et al.	12/29/1998	
	29	5,861,372		Folkman et al.	01/19/1999	
	30	5,885,795		O'Reilly et al.	03/23/1999	
	31	5,892,069		D'Amato et al.	04/06/1999	
	32	5,958,892		Mukhopadhyay et al.	09/28/1999	
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	34	6,046,186		Tanabe et al.	04/04/2000	
	35	6,054,598		Sachdeva et al.	04/25/2000	
	36	6,136,992		Ram et al.	10/24/2000	
	37	6,200,966		Stewart	03/13/2001	
	38	6,239,123		Green et al.	05/29/2001	
	39	6,284,789	B1	LaLonde et al.	09/04/2001	
	40	6,358,940	B1	Conney	03/19/2002	
	41	6,399,773	B1	Liu et al.	06/04/2002	
	42	6,410,029	B1	Mukhopadhyay et al.	06/25/2002	
	43	6,514,971	B1	Thomas et al.	02/04/2003	
	44	6,528,676	B1	D'Amato et al.	03/04/2003	
BZ	45	6,605,622	B2	Green et al.	08/12/2003	

Examiner Signature	Badio	Date Considered	5/10/05
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**FOREIGN PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>2</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
BB	46	DE	1907330	/	Sandoz Ltd. (Identifier only)	10/23/1969		
	47	DE	2 004 516		VEB Jenapharm	09/10/1970	English translation needed	No
	48	DE	27 57 157		Schering AG	12/19/1977	English translation needed	
	49	DE	3625315	/	Schering A.-G (Identifier only)	01/28/1988		
	50	EPO	0166937	/ A2	Abbott Laboratories	08/01/1986		
	51	GB	857,080		Syntex S.A.	12/29/1960		
	52	GB	857,081		Syntex S.A.	12/29/1960		
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	54	JP	42-928	/ B	DAINIPPON PHARM CO LTD (abstract only)	01/18/1967		
	55	JP	39-5480	/ B	Teikoku Hormone Mfg. Co.	3/25/61	English Abstract only	No
	56	JP	11-209322	/	Daiichi Sankyo et al.	08/03/1999	Abstract Only	No
	57	JP	58-131978		Lilly & Co Eli (Elii)	08/06/1983	English Abstract only	No
BB	58	JP	63090763	/ A	Research Development Corp. of Japan (Abstract only)	04/21/1988		

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		Office <sup>2</sup>	Number <sup>3</sup>	Kind Code <sup>2</sup> (if known)				
BB	59	JP	63-119500		Dai Ichi Seiyaku Co Ltd.	05/24/1988	English Abstract only	No
	60	JP	41 000100	A	Dainippon Pharmaceutical Co., Ltd. (abstract only)	01/07/1966		
	61	SU	1240038	A1	A MED ONCOLOGY CENTRE (abstract only)	10/27/1996		
	62	WO	00/07576	A2	ENDORECHERCHE, INC	02/17/2000		
	63	WO	00/10552	A2	Global Vascular Concepts, Inc.	03/02/2000		
	64	WO	87/02367	A3	The Upjohn Company	04/23/1987		
	65	WO	88/08002	A1	The Upjohn Company	10/20/1988		
	66	WO	93/19746	A1	ORION-YH-TYMA OY	10/14/1993		
	67	WO	95/04535	A1	The Children's Medical Center Corporation	02/16/1995		
	68	WO	98/32763	A1	SRJ International	07/30/1998		
	69	WO	98/40398		Pharm-Eco Laboratories, Inc.	09/17/1998		
	70	WO	99/01142	A1	Hyal Pharmaceutical Corporation	01/14/1999		
BB	71	WO	99/22728	A1	Arch Development Corporation	05/14/1999		

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		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)							
BB	72	WO	99/33858	A3	SRI International	07/08/1999					
	73	WO	99/33859	A2	SRI International	07/08/1999					
BB	74	WO	99/35150	A3	Arizona Board of Regents	07/15/1999					

Examiner Signature	<i>Badio</i>	Date Considered	5/10/05
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Attorney Docket Number	05213-0493 (43170-253692)

**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

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BTB	75	Author: Title: Liloipristone/(1-[4-(Dimethylamino)phenyl]-17-hydroxy-17-(3-hydroxy-1-propenyl)estra-4,9-diene-3-one; AK 98734 Publ: Dictionary of Drugs (1990), Dict. of Steroids (1991), Dict. of Org. Compds (6th Ed) (1996), Dict. of Pharm. Agents (1997) Vol/Iss: Pages: Date:	
	76	Author: Title: (paragraphs 583-584) Publ: The Merck Index 11th Edition Vol/Iss: Pages: 88 Date: 1989	
	77	Author: Title: Registry Number: 56933-77-8 Publ: Chemical Abstracts Vol/Iss: Pages: Date: 2003	
	78	Author: Title: Registry Number: 56933-78-9 Publ: Chemical Abstracts Vol/Iss: Pages: Date: 2003	
	79	Author: Title: Registry Number: 57380-15-1 Publ: Chemical Abstracts Vol/Iss: Pages: Date: 2003	
	80	Author: Title: Registry Number: 71782-94-0 Publ: Chemical Abstracts Vol/Iss: Pages: Date: 2003	
BB	81	Author: Title: Registry Number: 71782-95-1 Publ: Chemical Abstracts Vol/Iss: Pages: Date: 2003	

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Sheet 7 of 31				Attorney Docket Number	05213-0493 (43170-253692)

## OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

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BB	82	Author: Title: Registry Number: 101277-11-6  Publ: <u>Chemical Abstracts</u>  Vol/Iss: Pages: Date: 2003	
	83	Author: Title: News Article: Hoffman-La Roche Signs \$70 Million Deal with Millenium on Genomics Technology  Publ: <u>Genetic Engineering News</u>  Vol/Iss: Pages: Date: 4/15/1994	
	84	Author: Title: News Article: Advanced Drug Delivery Systems Peak Interest of Pharmaceutical & Biotech Firms  Publ: <u>Genetic Engineering News</u>  Vol/Iss: Pages: Date: 4/15/1994	
	85	Author: Title: News Article: Nasal Spray for Treating Bleeding Disorders  Publ: <u>Genetic Engineering News</u>  Vol/Iss: Pages: Date: 4/15/1994	
	86	Author: ABOULWafa et al. Title: Synthesis and evaluation for uterotrophic and antiimplantation activities of 2-substituted estradiol derivatives  Publ: <u>Steroids</u>  Vol/Iss: 57 Pages: 199-204 Date: 04/1992	
	87	Author: AIZU-YOKOTA et al. Title: Natural Estrogens Induce Modulation of Microtubules in Chinese Hamster V79 Cells in Culture  Publ: <u>Cancer Research</u>  Vol/Iss: 55 Pages: 1863-1868 Date: 05/01/95	
BB	88	Author: ALGIRE, G.H. et al. Title: Vascular reactions of normal and malignant tumors in vivo. I. Vascular reactions of mice to wounds and to normal and neoplastic transplants  Publ: <u>Journal of the National Cancer Institute</u>  Vol/Iss: 6 Pages: 73-85 Date: 08/1945	

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BB	89	Author: ALIEV et al. Title: 54929q Synthesis of cycloalkyl derivatives of dihydric phenols and their ethers Publ: Chemical Abstracts Vol/Iss: 72 Pages: 370 Date: 1970	
	90	Author: ANSTEAD et al. Title: The Estradiol Pharmacophore: Ligand Structure-Estrogen Receptor Binding Affinity Relationships and a Model for the Receptor Binding Site Publ: Steroids Vol/Iss: 62 Pages: 268-303 Date: 1997	
	91	Author: ARNOLDI et al. Title: Sweet Isovanillyl Derivatives: Synthesis and Structure-Taste Relationships of Conformationally Restricted Analogs (Abstract only) Publ: Journal of Agric. Food Chem. Vol/Iss: 46(10) Pages: 4002-4010 Date: 1998	
	92	Author: ATTALLA et al. Title: 2-Methoxyestradiol Arrests Cells in Mitosis without Depolymerizing Tubulin Publ: Biochemical and Biophysical Research Communications Vol/Iss: 228 Pages: 467-473 Date: 1996	
BB	93	Author: ATTALLA et al. Title: 2-Methoxyestradiol-Induced Phosphorylation of Bcl-2: Uncoupling from JNK/SAPK Activation (Abstract only) Publ: Biochemical and Biophysical Research Communications Vol/Iss: 247 (3) Pages: 616-619 Date: 6/29/1998	
	94	Author: AUDIER et al. Title: Orientation de la fragmentation en spectrometrie de masse par introduction de groupements fonctionnels. VII. - Etyletacetals de ceto-2-steroides Publ: Bulletin De La Societe Chimique De France Vol/Iss: 10 Pages: 3088-3090 Date: 1965 <i>English translation needed</i>	
BB	95	Author: AYALA et al. Title: The Induction of Accelerated Thymic Programmed Cell Death During Polymicrobial Sepsis: Control by Corticosteroids but not Tumor Necrosis Factor (Abstract only) Publ: Shock Vol/Iss: 3 (4) Pages: 259-267 Date: 04/1995	

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BB	96	Author: BANIK et al. Title: Orally Active Long-Acting Estrogen (AY-20,121) (3-(2-propynyloxy)-estra-1,3,5,(10)-triene-17. beta.-ol trimethylacetate) (Identifier only) Publ: Steroids Vol/Iss: 16 (3) Pages: 289-296 Date: 1970	
	97	Author: BARDON et al. Title: Steroid Receptor-Mediated Cytotoxicity of an Antiestrogen and an Antiprogesterin in Breast Cancer Cells (Abstract only) Publ: Cancer Research Vol/Iss: 47 (5) Pages: 1441-1448 Date: 03/01/87	
	98	Author: BARNES et al. Title: Tumor Necrosis Factor Production in Patients with Leprosy Publ: Infection and Immunity Vol/Iss: 60 (4) Pages: 1441-1446 Date: 04/1992	
	99	Author: BINDRA et al. Title: Studies in Antifertility Agents. 8. Seco Steroids. 2. 5,6-Secoestradiol and Some Related Compounds Publ: Journal of Medicinal Chemistry Vol/Iss: 18 (9) Pages: 921-925 Date: 1975	
	100	Author: BLAGOSKLONNY et al. Title: Raf-1/bcl-2 Phosphorylation: A Step from Microtubule Damage to Cell Death Publ: Cancer Research Vol/Iss: 57 Pages: 130-135 Date: 01/01/97	
BB	101	Author: BLICKENSTAFF et al. Title: Synthesis of Some Analogs of Estradiol Publ: Steroids Vol/Iss: 46 (4,5) Pages: 889-902 Date: 10/1985	
	102	Author: BOYCE et al. Title: Some Preliminary Synthetical Studies with 5,6,7,8-Tetrahydro-8-methylindane-1,5-dione Publ: Unknown Title needed Vol/Iss: Pages: 4547-4553 Date: 1960	

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BB	103	Author: BRANDI et al. Title: Bone endothelial cells as estrogen targets (Abstract only) Publ: Calcif. Tissue Int. Vol/Iss: 53 (5) Pages: 312-317 Date: 1993	
	104	Author: BREM, H. et al. Title: Interstitial chemotherapy with drug polymer implants for the treatment of recurrent gliomas Publ: Journal of Neurosurgery Vol/Iss: 74 Pages: 441-446 Date: 03/01/91	
	105	Author: BRODIE, A.M. Title: Aromatase Inhibitors in the Treatment of Breast Cancer (Abstract only) Publ: Journal of Steroid Biochemistry and Molecular Biology Vol/Iss: 49 (4-6) Pages: 281-287 Date: 06/1994	
	106	Author: BROSENS et al. Title: Comparative Study of the Estrogenic Effect of Ethinylestradiol and Mestranol on the Endometrium Publ: Laboratory for Gynecological Physiopathology Vol/Iss: 14 (6) Pages: 679-685 Date: 12/01/76	
	107	Author: BURROWS, N.P. Title: Thalidomide Modifies Disease Publ: British Medical Journal Vol/Iss: 307 (6909) Pages: 939-940 Date: 10/09/93	
	108	Author: CAMBIE et al. Title: Aromatic Steroids. Part II. Chromium Trioxide Oxidation of Some Oestra-1,3,5(10)-trienes Publ: Journal of the Chemical Society Vol/Iss: 9 Pages: 1234-1240 Date: 1969	
BB	109	Author: CAMBIE et al. Title: Aromatic Steroids. Part I. Oxidation Products of 3-Methoxyestra-1,3,5(10)-triene-17 $\beta$ -yl Acetate Publ: J. Chem. Soc. Vol/Iss: Pages: 2603-2608 Date: 1968	

Examiner Signature	Badio	Date Considered	8/10/05
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Application No.	09/780,650
Filing Date	02/12/2001
First Named Inventor	D'Amato
Group Art Unit	1616
Examiner Name	Badio, Barbara P.
Attorney Docket Number	05213-0493 (43170-253692)

Sheet 11 of 31

**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T*
BB	110	Author: CASTAGNETTA, L. et al. Title: Simple Approach to Measure Metabolic Pathways of Steroids in Living Cells Publ: Journal of Chromatography Vol/Iss: 572 Pages: 25-39 Date: 12/06/91	
	111	Author: CHASSEROT-GOLAZ et al. Title: Biotransformation of 17.β.-hydroxy-11.β.- (4-dimethylaminophenyl) 17.α.1-propynyl-estra-4,9-diene-3-one (RU486) in Rat Hepatoma Variants (Identifier only) Publ: Biochemical Pharmacology Vol/Iss: 46 (11) Pages: 2100-2103 Date: 1993	
	112	Author: CHEN et al. Title: A New Synthetic Route to 2- and 4-Methoxyestradiols by Nucleophilic Substitution Publ: Steroids Vol/Iss: 47 (1) Pages: 63-66 Date: 01/1986	
	113	Author: CHEN et al. Title: Synthesis of 11.β.- (4-dimethylaminophenyl)-17.β.-hydroxy-17.α.- (1-propynyl) estra-4, 9-dien-3-one (RU486) (Identifier only) Publ: Nanjing Yaoxueyuan Xuebao Vol/Iss: 17 (4) Pages: 282-285 Date: 1986	
	114	Author: COHEN et al. Title: Novel Total Synthesis of (+)-Estrone 3-Methyl Ether, (+)-13βEthyl-3-methoxygona-1,3,5(10)-trien-17-one, and (+)-Equilenin 3-Methyl Ether Publ: The Journal of Organic Chemistry Vol/Iss: 40 (6) Pages: 681-685 Date: 03/21/75	
	115	Author: COLLINS et al. Title: The Structure and Function of Estrogens. XI. Synthesis of (+/-)-7(8-11α) abeo-Estradiol and its 9,11-Didehydro Derivative Publ: Aust. Journal of Chemistry Vol/Iss: 45 (1) Pages: 71-97 Date: 1992	
BB	116	Author: COREY et al. Title: Applications of N,N-Dimethylhydrazones to Synthesis. Use in Efficient, Positionally and Stereochemically Selective C-C Bond Formation; Oxidative Hydrolysis to Carbonyl Compounds Publ: Tetrahedron Letters Vol/Iss: 1 Pages: 3-6 Date: 1976	

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First Named Inventor	D'Amato
Group Art Unit	1616
Examiner Name	Badio, Barbara P.
Attorney Docket Number	05213-0493 (43170-253692)

Sheet	12	of	31
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## OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

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BB	117	Author: COREY et al. Title: Facile Conversion of N,N-Dimethylhydrazones to Carbonyl Compounds by Cupric Ion-Catalyzed Hydrolysis Publ: Tetrahedron Letters Vol/Iss: 41 Pages: 36678-3668 Date: 1976	
	118	Author: CRABBE, P. Title: Cotton effect of the styrene chromophore (Abstract only) Publ: Chem. Ind. Vol/Iss: 27 Pages: 917-918 Date: 1969	
	119	Author: CUMMINGS et al. Title: Apoptosis Publ: The American Journal of Surgical Pathology Vol/Iss: 21 (1) Pages: 88-101 Date: 1997	
	120	Author: CUSHMAN et al. Title: Synthesis, Antitubulin and Antimitotic Activity, and Cytotoxicity of Analogs of 2-Methoxyestradiol, an Endogenous Mammalian Metabolite of Estradiol that Inhibits Tubulin Polymerization by Binding to the Colchicine Binding Site Publ: Journal of Medicinal Chemistry Vol/Iss: 38 (12) Pages: 2041-2049 Date: 06/09/95	
	121	Author: CUSHMAN et al. Title: Synthesis of Analogs of 2-Methoxyestradiol with Enhanced Inhibitory Effects on Tubulin Polymerization and Cancer Cell Growth Publ: Journal of Medicinal Chemistry Vol/Iss: 40 (15) Pages: 2323-2334 Date: 1997	
	122	Author: D'AMATO et al. Title: 2-Methoxyestradiol, an Endogenous Mammalian Metabolite, Inhibits Tubulin Polymerization by Interacting at the Colchicine Site Publ: Proceedings of the National Academy of Science USA Vol/Iss: 91 Pages: 3964-3968 Date: 04/26/1994	
BB	123	Author: D'AMATO, R.J. et al. Title: Thalidomide is an Inhibitor of Angiogenesis Publ: Proceedings of the National Academy of Science USA Vol/Iss: 91 Pages: 4082-4085 Date: 04/01/94	

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BB	124	Author: DING et al. Title: Sex Hormone-Binding Globulin Mediates Prostate Androgen Receptor Action via a Novel Signaling Pathway (Abstract only) Publ: Endocrinology Vol/Iss: 139 (1) Pages: 213-218 Date: 1998	
	125	Author: DURANI et al. Title: Seco-Oestradiols and Some Non-Steroidal Oestrogens: Structural Correlates of Oestrogenic Action Publ: Journal of Steroid Biochemistry Vol/Iss: 11 Pages: 67-77 Date: 1979	
	126	Author: DVIR et al. Title: Thin-layer Chromatography of DANSYL-oestrogens Publ: Journal of Chromatography Vol/Iss: 52 Pages: 505-506 Date: 11/04/70	
	127	Author: EDER et al. Title: Synthese von Ostradiol (in German - No translation available) Publ: Chem. Ber. English Abstract Only Vol/Iss: 109 Pages: 2948-2953 Date: 1976	
	128	Author: EL-TOMBARY. Title: Synthesis, Uterotropic, And Antiuterotropic Activities of Some Estradiol Derivatives Containing Thiadiazole, Thiazoline, and Thiazolidinone Moieties Publ: Arch. Pharm. Pharm. Med. Chem. Vol/Iss: 330 (9-10) Pages: 295-302 Date: 1997	
	129	Author: EMONS et al. Title: Modulation der hypophysären Sekretion von Luteinisierendem Hormon (LH) durch Oestrogene Publ: FOCUS MHL English Abstract Only Vol/Iss: 3 Pages: 221-228 Date: 1986	
BB	130	Author: EPE et al. Title: Microtubular Proteins as Cellular Targets for Carcinogenic Estrogens and Other Carcinogens Publ: Mechanisms of Chromosome Distribution and Aneuploidy Vol/Iss: Pages: 345-351 Date: 1989	

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				First Named Inventor	D'Amato
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BB	131	Author: FANCHENKO et al. Title: Characteristics of the guinea pig uterus estrogen receptor system (Abstract only) Publ: Byull. Eksp. Biol. Med. Vol/Iss: 85 (4) Pages: 467-470 Date: 1978			
	132	Author: FETIZON et al. Title: Synthesis of 2-keto steroids (Abstract only) Publ: Bull. Soc. Chim. FR. Vol/Iss: 8 Pages: 3301-3306 Date: 1968			
	133	Author: FEVIG et al. Title: A Short, Stereoselective Route to 16 $\alpha$ (Substituted-alkyl)estradiol Derivatives Publ: Journal of Organic Chemistry Vol/Iss: 52 Pages: 247-251 Date: 1987			
	134	Author: FIELD et al. Title: Effect of Thalidomide on the Graft versus Host Reaction Publ: Nature Vol/Iss: 211 (5055) Pages: 1308-1310 Date: 09/17/66			
	135	Author: FIESER et al. Title: N-Methylformanilide Publ: Organic Synthesis Collective Volume 3 Vol/Iss: 3 Pages: 590-591 Date: 1955			
	136	Author: FISHMAN, J. Title: Synthesis of 2-Methoxyestrogens Publ: Journal of the American Chemical Society Vol/Iss: 80 Pages: 1213-1216 Date: 03/05/98			
BB	137	Author: FLOHE et al. Title: Studies on the Hypothetical Relationship of Thalidomide-induced Embryopathy and Collagen Biosynthesis Publ: Arzneimittel/Forschung (Germany West) Vol/Iss: 31 (2) Pages: 315-320 Date: 01/01/81			

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				First Named Inventor	D'Amato
				Group Art Unit	1616
				Examiner Name	Badio, Barbara P.
Sheet	15	of	31	Attorney Docket Number	05213-0493 (43170-253692)

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BB	138	Author: FOLKMAN et al. Title: Angiogenesis Inhibition and Tumor Regression Caused by Heparin or a Heparin Fragment in the Presence of Cortisone  Publ: Science  Vol/Iss: 221 Pages: 719-725 Date: 08/19/83	
	139	Author: FOLKMAN, J. Title: Tumor Angiogenesis: Therapeutic Implications  Publ: New England Journal of Medicine  Vol/Iss: 285 (21) Pages: 1182-1186 Date: 11/18/71	
	140	Author: FOLKMAN, J. et al. Title: Induction of Angiogenesis During the Transition from Hyperplasia to Neoplasia  Publ: Nature  Vol/Iss: 339 Pages: 58-61 Date: 05/04/89	
	141	Author: FOLKMAN, J. et al. Title: Tumor Behavior in Isolated Perfused Organs in vitro Growth and Metastases of Biopsy Material in Rabbit Thyroid and Canine Intestinal Segment  Publ: Annals of Surgery  Vol/Iss: 164(3) Pages: 491-502 Date: 09/01/66	
	142	Author: FOTSIS et al. Title: The Endogenous Oestrogen Metabolite 2-Methoxyoestradiol Inhibits Angiogenesis and Suppresses Tumour Growth  Publ: Nature  Vol/Iss: 368 Pages: 237-239 Date: 03/17/94	
	143	Author: GADOSY et al. Title: Generation, Characterization, and Deprotonation of Phenol Radical Cations  Publ: Journal of Physical Chemistry  Vol/Iss: 103 Pages: 8834-8839 Date: 1999	
BB	144	Author: GANDHI et al. Title: Mannich Reaction of Estrone  Publ: Journal of Indian Chem. Soc.  Vol/Iss: 39 Pages: 306-308 Date: 1962	(Abstract only)

Examiner Signature	Badio	Date Considered	5/10/05
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BB	145	Author: GASLINI et al. Title: Reaction of Eugenol with Synthesis Gas. Synthesis of 5,6,7,8-Tetrahydro-3-methoxy-2-naphthol Publ: Journal of Organic Chemistry Vol/Iss: 29 (5) Pages: 1177-1180 Date: 05/1964	
	146	Author: GIMBRONE, M.A. et al. Title: Tumor Growth and Neovascularization: An Experimental Model Using the Rabbit Cornea Publ: Journal of the National Cancer Institute Vol/Iss: 52(2) Pages: 413-427 Date: 02/74	
	147	Author: GIMBRONE, M.A. et al. Title: Tumor dormancy <i>in vivo</i> by Prevention of Neovascularization Publ: Journal of Experimental Medicine Vol/Iss: 136 Pages: 261-276 Date: 1972	
	148	Author: GONZALEZ et al. Title: Synthesis and Pharmacological Evaluation of 8 $\alpha$ Estradiol Derivatives Publ: Steroids Vol/Iss: 40 (2) Pages: 171-187 Date: 9/1982	
	149	Author: GROSS, J.L. et al. Title: Modulation of Solid Tumor Growth <i>in vivo</i> by bFGF (Abstract only) Publ: Proceedings of the American Association of Cancer Research Vol/Iss: 31 Pages: 79 Date: 03/90	
	150	Author: GUJJAR et al. Title: The Effect of Estradiol on Candida albicans Growth Publ: Annals of Clinical and Laboratory Science Vol/Iss: 27 (2) Pages: 151-156 Date: 1997	
BB	151	Author: GUNZLER, V. Title: Thalidomide-A Therapy for the Immunological Consequences of HIV Infection? Publ: Medical Hypothesis Vol/Iss: 30 (2) Pages: 105-109 Date: 10/89	

Examiner  
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BB	152	Author: GUPTA et al. Title: Antifertility Agents. XIV. Secosteroids. VII. Synthesis of 2 $\alpha$ and 2 $\beta$ , 6 $\beta$ -dimethyl-3 $\beta$ -(p-hydroxyphenyl)-trans-bicyclo[4.3.0]nonan-7-ones and some related compounds (Abstract only) Publ: Indian Journal of Chemistry Vol/Iss: 13 (7) Pages: 759-760 Date: 1975	
	153	Author: GUPTA et al. Title: Studies in Antifertility Agents. Part XVIII. 2 $\alpha$ 6 $\beta$ -Diethyl-3 $\beta$ -(p-hydroxyphenyl)-trans-bicyclo[4.3.0]nonan-7 $\beta$ -ol and 6 $\beta$ -methyl-3 $\beta$ -(p-hydroxyphenyl)-2 $\alpha$ -propyl-trans-bicyclo[4.3.0]nonan-7 $\beta$ -ol (Abstract only) Publ: Indian Journal of Chemistry Vol/Iss: 19B (10) Pages: 886-890 Date: 1980	
	154	Author: GUTIERREZ-RODRIGUEZ et al. Title: Treatment of Refractory Rheumatoid Arthritis - The Thalidomide Experience Publ: The Journal of Rheumatology Vol/Iss: 16 (2) Pages: 158-163 Date: 02/89	
	155	Author: GUTIERREZ-RODRIGUEZ, O. Title: Thalidomide - A Promising New Treatment for Rheumatoid Arthritis Publ: Arthritis and Rheumatism Vol/Iss: 27 (10) Pages: 1118-1121 Date: 10/84	
	156	Author: HAHNEL et al. Title: The Specificity of the Estrogen Receptor of Human Uterus Publ: Journal of Steroid Biochemistry Vol/Iss: 4 Pages: 21-31 Date: 1973	
	157	Author: HALDAR et al. Title: Bcl2 is the Guardian of Microtubule Integrity Publ: Cancer Research Vol/Iss: 57 Pages: 229-233 Date: 01/15/97	
BB	158	Author: HAMEL et al. Title: Interactions of 2-Methoxyestradiol, an Endogenous Mammalian Metabolite, with Unpolymerized Tubulin and with Tubulin Polymers (Abstract only) Publ: Biochemistry Vol/Iss: 35 (4) Pages: 1304-1310 Date: 1996	

Examiner  
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BBS	159	Author: HANDLEY et al. Title: Chronic bullous disease of childhood and ulcerative colitis Publ: British Journal of Dermatology Vol/Iss: 127 (40) Pages: 67-68 Date: 07/01/92	
	160	Author: HE et al. Title: A Versatile Synthesis of 2-Methoxyestradiol, an Endogenous Metabolite of Estradiol which Inhibits Tubulin Polymerization by Binding to the Colchicine Binding Site Publ: Bioorganic & Medicinal Chemistry Letters Vol/Iss: 4 (14) Pages: 1724-1728 Date: 1994	
	161	Author: HE et al. Title: Novel Cytokine Release Inhibitors. Part II Steroids Publ: Bioorganic & Medicinal Chemistry Letters Vol/Iss: 8 Pages: 2825-2828 Date: 1998	
	162	Author: HEJAZ et al. Title: Synthesis and Biological Activity of the Superestrogen (E)-17-Oximino-3-O-sulfamoyl-1,3,5(10)-estratriene: X-ray Crystal Structure of (E)-17-Oximino-3-hydroxy-1,3,5(10)-estratriene Publ: Journal of Medicinal Chemistry Vol/Iss: 42 (16) Pages: 3188-3192 Date: 1999	
	163	Author: HENEY et al. Title: Thalidomide treatment for chronic graft-versus-host disease Publ: British Journal of Haematology Vol/Iss: 78 (1) Pages: 23-27 Date: 05/91	
	164	Author: HOLKER et al. Title: The Reactions of Estrogens with Benzeneseleninic Anhydride and Hexamethyldisilazane Publ: J. Chem. Soc. Perkin Trans. Vol/Iss: 1 Pages: 1915-1918 Date: 1982	
BBS	165	Author: HORI, A. et al. Title: Suppression of Solid Tumor Growth by Immunoneutralizing Monoclonal Antibody Against Human Basic Fibroblasts Growth Factor Publ: Cancer Research Vol/Iss: 51 Pages: 6180-6184 Date: 11/15/91	

Examiner Signature	<i>Badio</i>	Date Considered	5/10/05
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BB	166	Author: HU, G. Title: Neomycin Inhibits Angiogenin-induced Angiogenesis (abstract Only) Publ: Proceedings of the National Academy of Sciences, USA Vol/Iss: 95 (17) Pages: 9791-9795 Date: 1998	
	167	Author: Ikegawa et al. Title: Immunoaffinity extraction for liquid chromatographic determination of equilin and its metabolites in plasma (Abstract only) Publ: Biomed. Chromatogr. Vol/Iss: 10 (2) Pages: 73-77 Date: 1996	
	168	Author: IMAMURA et al. Title: Method for Manufacture of Dihydric Phenols (Abstract only) Publ: USPATFULL 76:20259 US 3,950,437 Vol/Iss: Pages: Date: 04/13/1976	
	169	Author: INGBER, D. et al. Title: Synthetic analogues of fumagillin that inhibit angiogenesis and suppress tumor growth Publ: Nature Vol/Iss: 348 Pages: 555-557 Date: 12/06/90	
	170	Author: IRIARTE et al. Title: Steroids (XCIV). Synthesis of 2-methyl and 1,2-dimethyl estrogens (Abstract only) Publ: Tetrahedron Vol/Iss: 3 Pages: 28-36 Date: 1958	
	171	Author: JAGGERS et al. Title: Potent Inhibitory Effects of Steroids in an in vitro Model of Angiogenesis (Abstract only) Publ: Journal of Endocrinology Vol/Iss: 150 (3) Pages: 457-464 Date: 1996	
BB	172	Author: JHINGRAN et al. Title: Studies in Antifertility Agents - Part XLI: Secosteroids-x: Syntheses of Various Stereoisomers of (+)-2,6 $\beta$ -diethyl-7 $\alpha$ -ethynyl-3-(p-hydroxyphenyl)-trans-bicyclo [4.3.0]nonan-7 $\beta$ -ol. Publ: Steroids Vol/Iss: 42 (6) Pages: 627-634 Date: 1983	

Examiner Signature	Badio	Date Considered	5/10/05
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'Unique citation designation number. 'See attached Kinds of U.S. Patent Documents. 'Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 'For Japanese patent document, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 'Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 'Applicant is to place a check mark here if English language translation is attached.

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Substitute for Form 1449/A/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary)				Complete if Known		
				Application No.	09/780,650	
				Filing Date	02/12/2001	
				First Named Inventor	D'Amato	
				Group Art Unit	1616	
				Examiner Name	Badio, Barbara P.	
Sheet	20	of	31	Attorney Docket Number		05213-0493 (43170-253692)

## OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T*
BB	173	Author: JOSEFSSON et al. Title: Suppression of Type II Collagen-Induced Arthritis by the Endogenous Estrogen Metabolite 2-Methoxyestradiol Publ: Arthritis & Rheumatism Vol/Iss: 40 (1) Pages: 154-163 Date: 01/1997	
	174	Author: KABARITY et al. Title: Further Investigations on the cytological effects of some contraceptives Publ: Mutation Research Vol/Iss: 135 Pages: 181-188 Date: 1984	
	175	Author: KARWAT Title: Separation and Recovery of Hydrogen Sulfide from Hydrocarbon Mixture Publ: Caplus DE 1103310 Vol/Iss: Pages: Date: 09/02/1959	
	176	Author: KATAOKA et al. Title: An Agent that Increases Tumor Suppressor Transgene Product Coupled with Systemic Transgene Delivery Inhibits Growth of Metastatic Lung Cancer in Vivo (Abstract only) Publ: Cancer Research Vol/Iss: 58 (21) Pages: 4761-4765 Date: 11/1998	
	177	Author: KELLY et al. Title: The Stimulation of Prostaglandin Production by Two Antiprogestosterone Steroids in Human Endometrial Cells (Abstract only) Publ: Journal of Clinical Endocrinology Metabolism Vol/Iss: 62 (6) Pages: 1116-1123 Date: 06/1986	
	178	Author: KIM, K.J. et al. Title: Inhibition of Vascular Endothelial Growth Factor-induced Angiogenesis Suppresses Tumor Growth In Vivo Publ: Nature Vol/Iss: 362 Pages: 841-844 Date: 04/29/93	
BB	179	Author: KLAUBER et al. Title: Inhibition of Angiogenesis and Breast Cancer in Mice by the Microtubule Inhibitors 2-Methoxyestradiol and Taxol Publ: Cancer Research Vol/Iss: 57 Pages: 81-86 Date: 01/01/97	

Examiner Signature	Badio	Date Considered	5/10/05
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				First Named Inventor	D'Amato
				Group Art Unit	1616
				Examiner Name	Badio, Barbara P.
Sheet	21	of	31	Attorney Docket Number	05213-0493 (43170-253692)

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BB	180	Author: KNIGHTON, D. et al. Title: Avascular and Vascular Phases of Tumour Growth in the Chick Embryo Publ: British Journal of Cancer Vol/Iss: 35 Pages: 347-356 Date: 1977	
	181	Author: KOLE et al. Title: Studies in Antifertility Agents. 11. Secosteroids. 5. Synthesis of 9,11-Secoestradiol Publ: Journal of Medicinal Chemistry Vol/Iss: 18 (7) Pages: 765-766 Date: 1975	
	182	Author: KOVACS et al. Title: Steroids. XXIII. Synthesis of 2- and 4-hydroxy and 2,4-dihydroxy derivatives of estrone and estradiol (Abstract only) Publ: Acta Phys.Chem. Vol/Iss: 19 (3) Pages: 287-290 Date: 1973	
	183	Author: LEBRAS, J. et al. Title: Activation and Regioselective Ortho-Functionalization of the A-Ring of B-Estradiol Promoted by "Cp*Ir": An Efficient Organometallic Procedure for the Synthesis of 2-Methoxyestradiol Publ: Organometallics Vol/Iss: 16 Pages: 1765-1771 Date: 1997	
	184	Author: LEWIS, Richard J. Title: Publ: Hawley's Condensed Chemical Dictionary Vol/Iss: Pages: 577 Date: 01/1993	
	185	Author: LEWIS, Richard J. Title: Publ: Hawley's Condensed Chemical Dictionary Vol/Iss: Pages: 128-129 Date: 01/1993	
BB	186	Author: LI, J., et al. Title: (DN 103:65176) Catechol Formation of Fluoro- and Bromo-substituted Estradiols by Hamster Liver Microsomes. Evidence for Dehalogenation. (Abstract only) Publ: CAPLUS: Molecular Pharmacology Vol/Iss: 27 (5) Pages: 559-565 Date: 1985	

Examiner Signature	Badio	Date Considered	07/10/05
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<sup>1</sup>Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent document, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language translation is attached.

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				Group Art Unit	1616
				Examiner Name	Badio, Barbara P.
Sheet	22	of	31	Attorney Docket Number	05213-0493 (43170-253692)

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	187	Author: LICHTENAUER et al. Title: Zur Behandlung des Prostata-Karzinoms Pub: <i>English translation needed</i> <u>Deutsches medizinisches Journal</u> Vol/Iss: 23 Pages: 248-249 Date: 01/1972	
BB	188	Author: LIEN, W. et al. Title: The blood supply of experimental liver metastases. II. A Microcirculatory study of the normal and tumor vessels of the liver with the use of perfused silicone rubber Pub: <u>Surgery</u> Vol/Iss: 68 (2) Pages: 334-340 Date: 08/1970	
	189	Author: LIMANTSEV et al. Title: Effect of some estrogen structural analogs on the development of the mouse embryo (Abstract only) Pub: <u>Akush Jinekol.</u> Vol/Iss: 6 Pages: 55-56 Date: 1982	
	190	Author: LIU et al. Title: Total Synthesis of (+)- $\Delta^{9(12)}$ Capnellene Pub: <u>Tetrahedron Letters</u> Vol/Iss: 26 (40) Pages: 4847-4850 Date: 1985	
	191	Author: LOOZEN et al. Title: An approach to the synthesis of 7.beta.-amino estrogens (Abstract only) Pub: <u>Recl.: J.R. Neth.Chem. Soc.</u> Vol/Iss: 102 (10) Pages: 433-437 Date: 1983	
	192	Author: LOTTERJNG et al. Title: 17 $\beta$ -Estradiol Metabolites Affect Some Regulators of the MCF-7 Cell Cycle Pub: <u>Cancer Letters</u> Vol/Iss: 110 Pages: 181-186 Date: 1996	
BB	193	Author: LOVELY et al. Title: 2-(Hydroxyalkyl)estradiols: Synthesis and Biological Evaluation Pub: <u>Journal of Medicinal Chemistry</u> Vol/Iss: 39 Pages: 1917-1923 Date: 1996	

Examiner Signature	<i>P. Badio</i>	Date Considered	<i>5/10/03</i>
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STATEMENT BY APPLICANT**

(use as many sheets as necessary)

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Application No.	09/780,650
Filing Date	02/12/2001
First Named Inventor	D'Amato
Group Art Unit	1616
Examiner Name	Badio, Barbara P.
Attorney Docket Number	05213-0493 (43170-253692)

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**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

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BB	194	Author: LUO et al. Title: Effect of Components of Growth Ether Copper(I)Iodide Mixed Catalyst on Nucleophilic Substitution of Bromoestrogen (Abstract No. 195225) Publ: Chemical Abstracts Vol/Iss: 111 (21) Pages: 818, Column 1 Date: 11/20/89	
	195	Author: MARO et al. Title: Mechanism of Polar Body Formation in the Mouse Oocyte: An Interaction Between the Chromosomes, the Cytoskeleton and the Plasma Membrane Publ: Journal of Embryology and Experimental Morphology Vol/Iss: 92 Pages: 11-32 Date: 1986	
	196	Author: MAYOL et al. Title: Ethynylestradiol-Induced Cell Proliferation in Rat Liver Involvement of Specific Populations of Hepatocytes (Abstract only) Publ: Carcinogenesis Vol/Iss: 13 (12) Pages: 2381-2388 Date: 1992	
	197	Author: MEIKRANTZ et al. Title: Apoptosis and the Cell Cycle Publ: Journal of Cellular Biochemistry Vol/Iss: 58 (2) Pages: 160-174 Date: 06/1995	
	198	Author: MEZA et al. Title: Managing the Gastrointestinal Complications of AIDS Publ: Drug Therapy Vol/Iss: 23 (11) Pages: 74-83 Date: 11/1993	
	199	Author: MICHEL et al. Title: Inhibition of synaptosomal high-affinity uptake of dopamine and serotonin by estrogen agonists and antagonists (Abstract only) Publ: Biochem. Pharmacol. Vol/Iss: 36 (19) Pages: 3175-3180 Date: 1987	
BB	200	Author: MILLER et al. Title: Synthesis and Structure-Activity Profiles of A-Homoestrans, the Estratropones Publ: Journal of Medicinal Chemistry Vol/Iss: 40 Pages: 3836-3841 Date: 1997	

Examiner Signature	Badio	Date Considered	5/10/05
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## Complete if Known

Sheet	24	of	31	Application No.	09/780,650
				Filing Date	02/12/2001
				First Named Inventor	D'Amato
				Group Art Unit	1616
				Examiner Name	Badio, Barbara P.
				Attorney Docket Number	05213-0493 (43170-253692)

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BB	201	Author: MILLER, Thomas Title: Tubulin as a Therapeutic Target (Abstract only) Publ: Dissertations Abstracts International Vol/Iss: 5907B Pages: 3454 Date: 1998	
	202	Author: MORISAKI et al. Title: Steroids. L1. Aromatization reaction of the cross-conjugated dienone system by Zinc 9. (Abstract only) Publ: Chem. Pharm. Bull. Vol/Iss: 14 (8) Pages: 866-872 Date: 1966	
	203	Author: MUKHOPADHYAY et al. Title: Induction of Apoptosis in Human Lung Cancer Cells after Wild-Type p53 Activation by Methoxyestradiol Publ: Oncogene Vol/Iss: 14 Pages: 379-384 Date: 1997	
	204	Author: NAAFS et al. Title: Thalidomide Therapy An Open Trial Publ: International Journal of Dermatology Vol/Iss: 24 (2) Pages: 131-134 Date: 03/1985	
	205	Author: NAKAGAWA-YAGI et al. Title: The Endogenous Estrogen Metabolite 2-Methoxyestradiol Induces Apoptotic Neuronal Cell Death <i>In Vitro</i> Publ: Life Sciences Vol/Iss: 58 (17) Pages: 1461-1467 Date: 1996	
	206	Author: NAMBARA et al. Title: Studies on Steroid Conjugates. III. New Synthesis of 2-Methoxyestrogens Publ: Chem. Pharm. Bulletin Vol/Iss: 18 (3) Pages: 474-480 Date: 03/1970	
BB	207	Author: NAMBARA et al. Title: Microbial transformation products derived from steroids. I. Synthesis of 1,2- and 3-dimethoxy-4-methylestratrienes (Abstract only) Publ: Chem. Pharm. Bull. Vol/Iss: 20 (2) Pages: 336-342 Date: 1972	

Examiner Signature	<i>Badio</i>	Date Considered	5/10/05
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				Application No.	09/780,650
				Filing Date	02/12/2001
				First Named Inventor	D'Amato
				Group Art Unit	1616
				Examiner Name	Badio, Barbara P.
Sheet 25 of 31				Attorney Docket Number	05213-0493 (43170-253692)
OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published			T*
BB	208	Author: NAMBARA et al. Title: Synthesis of 16 $\beta$ -Oxygenated Catechol Estrogen Methyl Ethers, New and Potential Metabolites Publ: Chemical & Pharmaceutical Bulletin Vol/Iss: 23 (7) Pages: 1613-1616 Date: 07/1975			
	209	Author: NAMBARA, T., et al. Title: DN 82:43650; Analytical Chemical Studies on Steroids. LXXIII. Synthesis of Epimeric 2-Hydroxy-16-Chlorestrogon Monomethyl Ethers (Abstract only) Publ: HCAPLUS-Chemical and Pharmaceutical Bulletin Vol/Iss: 22 (10) Pages: 2455-2457 Date: 1974			
	210	Author: NAPOLITANO et al. Title: 11 Beta-Substituted Estradiol Derivatives. 2. Potential Carbon-11 and Iodine-Labeled Probes for the Estrogen Receptor (Abstract only) Publ: Journal of Medicinal Chemistry Vol/Iss: 38 (14) Pages: 2774-2779 Date: 07/07/95			
	211	Author: NEWKOME et al. Title: Synthesis of Simple Hydrazones of Carbonyl Compounds by an Exchange Reaction Publ: Journal of Organic Chemistry Vol/Iss: 31 Pages: 677-681 Date: 03/1966			
	212	Author: NGUYEN, M. et al. Title: Elevated Levels of the Angiogenic Peptide Basic Fibroblast Growth Factor in Urine of Bladder Cancer Patients Publ: Journal of the National Cancer Institute Vol/Iss: 85 (3) Pages: 241-242 Date: 02/03/93			
	213	Author: NISHIGAKI et al. Title: Anti-Proliferative Effect of 2-Methoxyestradiol on Cultured Smooth Muscle Cells from Rabbit Aorta Publ: Atherosclerosis Vol/Iss: 113 Pages: 167-170 Date: 1995			
BB	214	Author: NUMAZAWA et al. Title: Efficient Synthesis of 2-Methoxy- and 4-Methoxy-Estrogens Publ: Journal of the Chemical Society Vol/Iss: Pages: 533-534 Date: 01/01/83			

Examiner Signature	<i>Barbara P. Badio</i>	Date Considered	5/10/05
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\*Unique citation designation number. \*See attached Kinds of U.S. Patent Documents. \*Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). \*For Japanese patent document, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. \*Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. \*Applicant is to place a check mark here if English language translation is attached.

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Substitute for Form 1449/A/PTO		SEP 29 2004 10253304 INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete if Known	
Application No.		09/780,650		Filing Date	
02/12/2001		First Named Inventor		D'Amato	
Group Art Unit		1616		Examiner Name	
Badio, Barbara P.		Attorney Docket Number		05213-0493 (43170-253692)	
Sheet	26	of	31		
OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published			T*
BB	215	Author: NUMAZAWA et al. Title: Novel and Regiospecific Synthesis of 2-Amino Estrogens via Zincke Nitration Publ: Steroids Vol/Iss: 41 (5) Pages: 675-682 Date: 1983			
	216	Author: OCHS et al. Title: Effect of Tumor Promoting Contraceptive Steroids on Growth and Drug Metabolizing Enzymes in Rat Liver (Abstract only) Publ: Cancer Research Vol/Iss: 46 (3) Pages: 1224-1232 Date: 1986			
	217	Author: OMAR et al. Title: Synthesis, binding affinities and uterotrophic activity of some 2-substituted estradiol and ring-A-fused pyrone derivatives Publ: European Journal of Medicinal Chemistry Vol/Iss: 29 Pages: 25-32 Date: 1994			
	218	Author: PARTHASARATHY et al. Title: Antioxidant: A New Role for RU-486 and Related Compounds (Abstract only) Publ: Journal of Clinical Investigation Vol/Iss: 94 (5) Pages: 1990-1995 Date: 11/1994			
	219	Author: PERT et al. Title: Preparations of 2,4-disubstituted estradiols (Abstract only) Publ: Australian Journal of Chemistry Vol/Iss: 42 (3) Pages: 421-432 Date: 1989			
220	Author: PETERS et al. Title: 17-Desoxy Estrogen Analogues Publ: Journal of Medicinal Chemistry Vol/Iss: 32 (7) Pages: 1642-1652 Date: 1989				
BB	221	Author: PFEIFFER et al. Title: Are catechol estrogens obligatory mediators of estrogen action in the central nervous system? I. Characterization of pharmacological probes with different receptor binding affinities and catechol estrogen formation rates (Abstract only) Publ: Journal of Endocrinology Vol/Iss: 110 (3) Pages: 489-497 Date: 1986			

Examiner Signature	<i>Padio</i>	Date Considered	5/10/05
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Sheet 27 of 31

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BB	222	Author: POWELL et al. Title: Investigation and Treatment of Orogenital Ulceration; studies on a Possible Mode of Action of Thalidomide Publ: British Journal of Dermatology Vol/Iss: 113 Supp. 28 Pages: 141-144 Date: 07/1985	
/	223	Author: RAO et al. Title: A Novel, Two-Step Synthesis of 2-Methoxyestradiol Publ: Synthesis Vol/Iss: Pages: 168-169 Date: 03/01/77	
	224	Author: ROMANELLI et al. Title: Ethyl-p-Dimethylaminophenylacetate Publ: Organic Synthesis Vol/Iss: 5 Pages: 552 Date: 10/24/1973	
/	225	Author: SAKAKIBARA, KYOICHI Title: 2-Hydroxy-1,3,5(10)-estratriene derivatives (Abstract only) (Identifier: XP-002186126) Publ: Chemical Abstracts Vol/Iss: 60(1) Pages: Date: 01/06/64	
/	226	Author: SATO et al. Title: Natural estrogens induce modulation of microtubules in Chinese hamster V79 cells in culture (Abstract only) Publ: Horm. Carcinog. II. Proceedings Int. Symp., 2nd (1996), Meeting Date 1994 Vol/Iss: Pages: 454-457 Date: 1996	
/	227	Author: SEEGERs et al. Title: The Mammalian Metabolite, 2-methoxyestradiol, Affects P53 Levels and Apoptosis Induction in Transformed Cells but Not in Normal Cells (Abstract only) Publ: Journal of Steroid Biochemistry and Molecular Biology Vol/Iss: 62 (4) Pages: 253-267 Date: 07/1997	
BB	228	Author: SHAH et al. Title: (+/-)-(N-alkylamino)benzazepine Analogs: Novel Dopamine D1 Receptor Antagonists (Abstract only) Publ: Journal of Medicinal Chemistry Vol/Iss: 38 (21) Pages: 4284-4293 Date: 10/13/95	

Examiner  
Signature

P. Badio

Date  
Considered

5/10/05

<sup>1</sup>Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the (two-letter code (WIPO Standard ST.3)). <sup>4</sup>For Japanese patent document, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language translation is attached.

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Sheet 28 of 31				Attorney Docket Number	05213-0493 (43170-253692)
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BB	229	Author: SHISHKINA et al. Title: Synthesis and properties of condensed heterocyclic derivatives of estra-4, 9-dien-17.beta.-ol-3-one (Abstract only) Publ: Khim.-Farm. Zh. Vol/Iss: 8 (1) Pages: 7-11 Date: 1974			
	230	Author: SIDKY et al. Title: Inhibition of Angiogenesis by Interferons: Effects on Tumor- and Lymphocyte-induced Vascular Responses Publ: Cancer Research Vol/Iss: 47 Pages: 5155-5161 Date: 10/01/87			
	231	Author: SIRACUSA et al. Title: The Effect of Microtubule- and Microfilament-disrupting Drugs on Preimplantation Mouse Embryos (abstract Only) Publ: Journal of Embryology and Experimental Morphology Vol/Iss: 60 Pages: 71-82 Date: 12/1980			
	232	Author: SPYRJOUNIS et al. Title: Copper (II) complex of an estradiol derivative with potent antiinflammatory properties (Abstract only) Publ: Arch. Pharm. Vol/Iss: 324 (9) Pages: 533-536 Date: 1991			
	233	Author: SRIVASTAVA, A. et al. Title: The Prognostic Significance of Tumor Vascularity in Intermediate-Thickness (0.76-4.0 mm Thick) Skin Melanoma Publ: American Journal of Pathology Vol/Iss: 133 (2) Pages: 419-424 Date: 11/1988			
	234	Author: STARKOV et al. Title: Mono- and Dialkylolation of Guaiacol by Olefins on KU-2 Cation Exchanger (Abstract only) Publ: Zhurnal Prikladnoi Khimii Vol/Iss: 41 (3) Pages: 688-690 Date: 1968			
BB	235	Author: TAYLOR, S. et al. Title: Protamine is an Inhibitor of Angiogenesis Publ: Nature Vol/Iss: 297 Pages: 307-312 Date: 05/27/82			

Examiner Signature	Badio	Date Considered	5/10/05
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\*Unique citation designation number. \*See attached Kinds of U.S. Patent Documents. \*Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). \*For Japanese patent document, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. \*Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. \*Applicant is to place a check mark here if English language translation is attached.

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Substitute for Form 1449/A/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary)				Complete if Known	
				Application No.	09/780,650
				Filing Date	02/12/2001
				First Named Inventor	D'Amato
				Group Art Unit	1616
				Examiner Name	Badio, Barbara P.
Sheet 29 of 31				Attorney Docket Number	05213-0493 (43170-253692)
OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published			T*
BB	236	Author: TERANISHI, M. et al. Title: Methylation of Catechol Estrogen with Diazomethane Publ: Chemical and Pharmaceutical Bulletin Vol/Iss: 31 (9) Pages: 3309-3314 Date: 09/1983			
	237	Author: TISHLER et al. Title: Microtubule-Active Drugs Taxol, Vinblastine, and Nocodazole Increase the Levels of Transcriptionally Active p53 Publ: Cancer Research Vol/Iss: 55 Pages: 6021-6025 Date: 12/15/95			
	238	Author: TREMBLAY et al. Title: A Convenient Synthetic Method for Alpha-Alkylation of Steroidal 17-Ketone: Preparation of 16 $\beta$ -(THPO-Heptyl)-Estradiol Publ: Synthetic Communications Vol/Iss: 25 (16) Pages: 2483-2495 Date: 1995			
	239	Author: TREMBLAY et al. Title: Synthesis of 16-(Bromoalkyl)-Estradiols Having Inhibitory Effect on Human Placental Estradiol 17 $\beta$ -Hydroxysteroid Dehydrogenase (17 $\beta$ HSD Type 1) Publ: Bioorganic & Medicinal Chemistry Vol/Iss: 3 (5) Pages: 505-523 Date: 1995			
	240	Author: UTNE et al. Title: The Synthesis of 2- and 4-Fluoroestradiol Publ: Journal of Organic Chemistry Vol/Iss: 33 (6) Pages: 2469-2473 Date: 06/1968			
	241	Author: VAN GEERESTEIN et al. Title: Structure of 11. $\beta$ -(4-(dimethylamino)phenyl)-17. $\beta$ -(hydroxy-17. $\alpha$ -(2-propenyl) estro-4,9-dien-3-one (Identifier only) Publ: Acta Crystallogr., Sect. C: Cryst. Struct. Commun. Vol/Iss: C43 (2) Pages: 319-322 Date: 1987			
BB	242	Author: VICENTE et al. Title: In Vitro Activity of Thalidomide Against Mycobacterium avium Complex Publ: Archives of Internal Medicine Vol/Iss: 153 (4) Pages: 534 Date: 02/22/93			

Examiner Signature	<i>Badio</i>	Date Considered	<i>5/10/05</i>
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				Filing Date	02/12/2001
				First Named Inventor	D'Amato
				Group Art Unit	1616
				Examiner Name	Badio, Barbara P.
Sheet	30	of	31	Attorney Docket Number	05213-0493 (43170-253692)
OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published			T*
BB	243	Author: WANG et al. Title: Photoaffinity Labeling of Human Placental Estradiol 17 $\beta$ -dehydrogenase with 2- And 4-azidoestrone, 2- and 4-azidoestradiol (abstract Only) Publ: Shengwu Huaxue Zazhi Vol/Iss: 8 (6) Pages: 715-718 Date: 1992			
	244	Author: WANG, Z. et al. Title: An Optimized Synthesis of 2-Methoxyestradiol, a Naturally Occurring Human Metabolite with Anticancer Activity Publ: Synth Commun. Vol/Iss: 28 (23) Pages: 4431-4437 Date: 1998			
	245	Author: WEIDNER, N. et al. Title: Tumor angiogenesis: A New Significant and Independent Prognostic Indicator in Early-Stage Breast Carcinoma Publ: Journal of the National Cancer Institute Vol/Iss: 84 Pages: 1875-1887 Date: 12/16/92			
	246	Author: WEIDNER, N. et al. Title: Tumor Angiogenesis Correlates with Metastasis in Invasive Prostate Carcinoma Publ: American Journal of Pathology Vol/Iss: 143 (2) Pages: 401-409 Date: 08/1993			
	247	Author: WEIDNER, N. et al. Title: Tumor Angiogenesis and Metastasis-Correlation in Invasive Breast Carcinoma Publ: New England Journal of Medicine Vol/Iss: 324 (1) Pages: 1-8 Date: 01/03/91			
	248	Author: WELSCH et al. Title: Staphylostatic Activity of Some New Diphenols, Naphthols, and Chalcones (Abstract only) Publ: Experientia Vol/Iss: 11 Pages: 350-351 Date: 1955			
BB	249	Author: WHITE et al. Title: Treatment of Pulmonary Hemangiomatosis with Recombinant Interferon Alfa-2a Publ: The New England Journal of Medicine Vol/Iss: 32 (18) Pages: 1197-1200 Date: 05/04/89			

Examiner Signature	Badio	Date Considered	5/10/05
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STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet

31

of

31

## Complete if Known

Application No.	09/780,650
Filing Date	02/12/2001
First Named Inventor	D'Amato
Group Art Unit	1616
Examiner Name	Badio, Barbara P.
Attorney Docket Number	05213-0493 (43170-253692)

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BB	250	Author: WIESE et al. Title: Induction of the Estrogen Specific Mitogenic Response of MCF-7 Cells by Selected Analogues of Estradiol-17 $\beta$ : A 3D QSAR Study Publ: Journal of Medicinal Chemistry Vol/Iss: 40 Pages: 3659-3669 Date: 1997	
	251	Author: WURTZ et al. Title: Three-Dimensional Models of Estrogen Receptor Ligand Binding Domain Complexes Based on Related Crystal Structures and Mutational and Structure-Activity Relationship Data Publ: Journal of Medicinal Chemistry Vol/Iss: 41 Pages: 1803-1814 Date: 1998	
	252	Author: YASUDA et al. Title: Accelerated differentiation in seminiferous tubules of fetal mice prenatally exposed to ethinyl estradiol (Abstract only) Publ: Anat. Embryol. (Berl.) Vol/Iss: 174 (3) Pages: 289-299 Date: 1986	
BB	253	Author: YUE et al. Title: 2-Methoxyestradiol, an Endogenous Estrogen Metabolite, Induces Apoptosis in Endothelial Cells and Inhibits Angiogenesis: Possible Role for Stress-Activated Protein Kinase Signaling Pathway and Fas Expression Publ: Molecular Pharmacology Vol/Iss: 51 Pages: 951-962 Date: 1997	

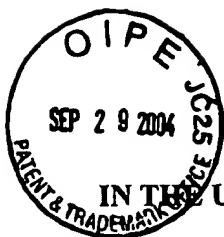
Examiner  
Signature

Badio

Date  
Considered

5/10/05

Unique citation designation number. \*See attached Kinds of U.S. Patent Documents. \*Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). \*For Japanese patent document, the indication of the year of the reign of the Emperor must precede the serial number of the document. \*Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. \*Applicant place a check mark here if English language translation is attached.



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

D'AMATO ET AL.

Serial No. 09/780,650

Filed: FEBRUARY 12, 2001

For: ESTROGENIC COMPOUNDS AS ANTI-MITOTIC AGENTS

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) Art Unit: 1616  
)  
) Examiner: BADIO, B.  
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APPENDIX A

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

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OCT 01 2004  
OFFICE OF PETITIONS

Sir:

Applicants respectfully request that the Examiner review the below-listed patent applications. Please review and initial each listed application and return a copy of the initialed Supplemental Appendix A to the Applicants.

The serial numbers of the below-listed U.S. patent applications are listed on this form as provided in MPEP §609(D), rather than a PTO-1449 form, to avoid the serial numbers of the pending U.S. patent applications being published on any patent that may issue from this application. Applicants do not waive the confidential nature of any of the below-listed patent applications.

- BB 1. U.S. Application Serial No. 09/641,327 filed August 18, 2000  
| 2. U.S. Application Serial No. 09/644,387 filed August 23, 2000  
| 3. U.S. Application Serial No. 09/779,331 filed February 8, 2001  
| 4. U.S. Application Serial No. 09/899,702 filed July 5, 2001  
| 5. U.S. Application Serial No. 09/939,208 filed August 24, 2001  
BB 6. U.S. Application Serial No. 10/077,142 filed February 15, 2002

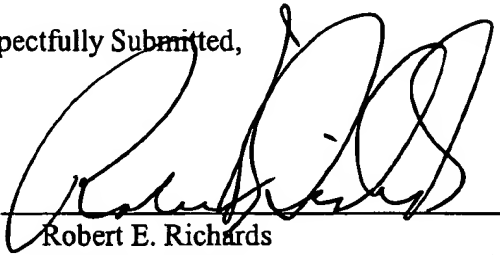


Our Docket: 05213-0493 (43170-253692)  
Filed: February 12, 2001

- BB 7 U.S. Application Serial No. 10/080,076 filed February 21, 2002
- 8 U.S. Application Serial No. 10/281,831 filed October 25, 2002
- 9 U.S. Application Serial No. 10/354,921 filed January 30, 2003
- 10 U.S. Application Serial No. 10/354,927 filed January 30, 2003
- 11 U.S. Application Serial No. 10/375,890 filed February 27, 2003
12. U.S. Application Serial No. 10/610,748 filed July 1, 2003
13. U.S. Application Serial No. 10/617,150 filed July 10, 2003
14. U.S. Application Serial No. 10/635,846 filed August 5, 2003
- BB 15 Unassigned U. S. Application filed February 27, 2004 under Attorney  
Docket No: 05213-3001 (43170-295490)

Respectfully Submitted,

By:

  
Robert E. Richards  
Reg. No. 29,105

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Suite 2800  
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Our Docket: 052130-0493 (43170-253692)

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				Filing Date	02/12/2001	
				First Named Inventor	D'Amato et al.	
				Group Art Unit	1616	
				Examiner Name	Badio, Barbara P.	
Sheet 1 of 1				Attorney Docket Number	05213-0493 (43710-253692)	
<b>U.S. PATENT DOCUMENTS</b>						
Examiner Initials	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)			
BB	1	4,444,767		Torelli et al.	04/24/1984	

Examiner Signature	Badio	Date Considered	5/10/05
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<sup>1</sup>Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent document, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language translation is attached.